



PATENT
Docket No.: 2809/1331

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants :	Molino et al.)	Examiner:
)	Marcela M. Cordero
Serial No. :	10/802,013)	Garcia
)	
Cnfrm. No. :	4932)	Art Unit:
)	1654
Filed :	March 16, 2004)	
)	
For :	NOVEL CYCLOSPORINS)	

**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98**

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97-1.98, applicants hereby bring to the attention of the U.S. Patent and Trademark Office, the references listed on the attached PTO/SB/08A form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patent and patent application publications (i.e., Reference Cite Nos. 1-21) are not enclosed. Copies of the other listed references (i.e., Reference Cite Nos. 22-277) are enclosed herewith.

Pursuant to 37 C.F.R. §§ 1.17(p) and 1.97(c), enclosed is a check to cover the required \$180.00 filing fee. The Commissioner is hereby authorized to charge any additional fees, or credit any overpayment to Deposit Account No. 14-1138.

Respectfully submitted,

Date: October 17, 2006

Alice Y. Choi

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CFR § 1.8(a)]

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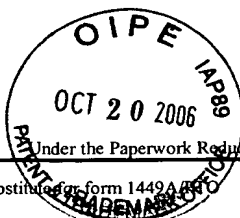
- ☒ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

October 17, 2006

Date

Ruth R. Smith

Ruth R. Smith



Substituted for form 1449 A (Rev. 10/90) INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known			
				Application Number		10/802,013	
				Filing Date		March 16, 2004	
				First Named Inventor		Molino	
				Art Unit		1654	
				Examiner Name		Marcela M. Cordero Garcia	
Sheet	1	of	19	Attorney Docket Number		2809/1331	
U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number - Kind Code ² (if known)					
	1	US-4,210,581		07-01-1980	Riiegger et al.		
	2	US-4,727,035		02-23-1988	Mahoney		
	3	US-5,318,901		06-07-1994	Patchett et al.		
	4	US-5,834,266		11-10-1998	Crabtree et al.		
	5	US-5,840,900		11-24-1998	Greenwald et al.		
	6	US-5,846,514		12-08-1998	Foster et al.		
	7	US-5,869,337		02-09-1999	Crabtree et al.		
	8	US-6,998,385		02-14-2006	Naicker et al.		
	9	US-7,012,064 B2		03-14-2006	Or et al.		
	10	US-7,012,065 B2		03-14-2006	Or et al.		
	11	US-7,060,672 B2		06-13-2006	Naicker et al.		
	12	US-2002/0128470 A1		09-12-2002	Fuenfschilling et al.		
	13	US-2002/0127198 A1		09-12-2002	Rothbard et al.		
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	15	US-2004/0087496 A1		05-06-2004	Kim et al.		
	16	US-2006/0035821 A1		02-16-2006	Hunt et al.		
	17	US-2006/0035822 A1		02-16-2006	Hunt et al.		
	18	US-2006/0052290 A1		03-09-2006	Naicker et al.		
	19	US-2006/0074015 A1		04-06-2006	Molino et al.		
	20	US-2006/0135414 A1		06-22-2006	Naicker et al.		
	21	US-2006/0217309		09-28-2003	Naicker et al.		
FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴	Kind Code ⁵ (if known)				
	22	BR 9603738-5 A		05-26-1998	Boelsterli et al.		Abstract only
	23	CA 1106303 A2		08-04-1981	Sandoz A.-G.		Abstract only
	24	CA 1292962 C		12-10-1991	Marshall		Abstract only
	25	CA 2076291 AA		02-20-1993	Syntex (U.S.A.) Inc.		Abstract only
	26	CA 2086267 AA		06-25-1994	University of Western Ontario		Abstract only
	27	CA 2096892 A		11-26-1993	Szanya		Abstract only
	28	CH 628872 A		03-31-1982	Sandoz A.-G.		Abstract only
	29	CH 630061 A		05-28-1982	Sandoz A.-G.		Abstract only
Examiner Signature					Date Considered		

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at 222.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known			
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				First Named Inventor		Molino	
				Art Unit		1654	
Examiner Name		Marcela M. Cordero Garcia		Attorney Docket Number		2809/1331	
Sheet	2	of	19				
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		Country Code ³	Number ⁴ Kind Code ² (if known)				
	30	CH	630062 A	05-28-1982	Sandoz A.-G.		Abstract only
	31	CH	637123 A	07-15-1983	Sandoz A.-G.		Abstract only
	32	CH	640520 A	01-13-1984	Sandoz, Inc.		Abstract only
	33	CS	277471 B6	03-17-1993	Czech Rep.		Abstract only
	34	CS	277472 B6	03-17-1993	Czech Rep.		Abstract only
	35	CZ	280552 B6	02-14-1996	Galena		Abstract only
	36	CZ	280553 B6	02-14-1996	Galena		Abstract only
	37	DD	285793 A5	01-03-1991	VEB Arzneimittelwerk		Abstract only
	38	DD	295245 A5	10-24-1991	Humboldt-Universitaet zu Berlin		Abstract only
	39	DD	295870 A	11-14-1991	Arzneimittelw Dresd		Abstract only
	40	DD	295871 A	11-14-1991	Arzneimittelw Dresd		Abstract only
	41	DE	2455859 A1	06-12-1975	Sandoz-Patent-G.m.b.H.		Abstract only
	42	DE	2648121 A1	05-12-1977	Sandoz-Patent-G.m.b.H.		Abstract only
	43	DE	2819094 A1	11-23-1978	Sandoz-Patent-G.m.b.H.		Abstract only
	44	DE	4032268 A1	04-16-1992	Boehringer Ingelheim, Kg		Abstract only
	45	DE	4236237 A1	04-28-1994	Behringwerke AG		Abstract only
	46	DE	19933173 A1	01-18-2001	Merck Patent G.m.b.H.		Abstract only
	47	DE	102004011988 A1	09-22-2005	Max-Planck-Gesellschaft zur Forderung der Wissenschaften e.V.		Abstract only
	48	EP	283801 A2	09-28-1988	Abbott Laboratories		Abstract only
	49	EP	300785 A2	01-25-1989	National Research Development Corp.		Abstract only
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Examiner Initials	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	50	EP	375454 A1	06-27-1990	du Pont de Nemours, E. I., and Co.		Abstract only
	51	EP	444897 A1	09-04-1991	Merck and Co., Inc.		Abstract only
	52	EP	471295 A1	02-19-1992	Abbott Laboratories		Abstract only
	53	EP	473961 A2	03-11-1992	Abbott Laboratories		Abstract only
	54	EP	487289 A2	05-27-1992	Syntex (U.S.A.) Inc.		Abstract only
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	56	FR	2640641 A1	06-22-1990	Biogal Gyogyszergyar		Abstract only
	57	FR	2757520 A1	06-26-1998	Rhone-Poulenc Rorer SA		Abstract only
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	59	FR	2757522 A1	06-26-1998	Rhone-Poulenc Rorer SA		Abstract only
	60	FR	2851471 A1	08-27-2004	Synt:em		Abstract only
	61	GB	2205317 A1	12-07-1988	Merck and Co., Inc.		Abstract only
	62	GB	2206119 A1	12-29-1988	Merck and Co., Inc.		Abstract only
	63	GB	2207678 A1	02-08-1989	Merck and Co., Inc.		Abstract only
	64	GB	2212499 A1	07-26-1989	Merck and Co., Inc.		Abstract only
	65	GB	2227244 A1	07-25-1990	Merck and Co., Inc.		Abstract only
	66	JP	57063093 A2	04-16-1982	Mitsubishi Chemical Industries Co., Ltd.		Abstract only
	67	JP	05271267 A2	10-19-1993	Fujisawa Pharmaceutical Co.		Abstract only
	68	JP	07278187 A2	10-24-1995	Nippon Shinyaku Co. Ltd.		Abstract only
	69	JP	10279596 A2	10-20-1998	Nippon Shinyaku Co. Ltd.		Abstract only
	70	JP	2002080394 A2	03-19-2002	LG Chemical Co., Ltd.		Abstract only
Examiner Signature					Date Considered		

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		Country Code ²	Number ³ Kind Code ⁵ (if known)				
	71	JP	2005198543 A2	07-28-2005	Mercian Corp.		Abstract only
	72	JP	2005325061 A2	11-24-2005	Nippon Rikagaku Yakuhin Co., Ltd.		Abstract only
	73	KR	161664 B1	11-16-1998	Cheil Foods and Chemicals Co., Ltd.		Abstract only
	74	KR	2002089300 A	11-29-2002	LG Household & Health Care Ltd.		Abstract only
	75	RU	2144017 C1	01-10-2000	Institut Molekulyarnoi Genetiki RAN		Abstract only
	76	WO	1990/006763	06-28-1990	The Trustees of Columbia University in the City of New York		
	77	WO	1992/006998	04-30-1992	Boehringer Ingelheim International GMBH		Abstract only
	78	WO	1992/013094	08-06-1992	Fujisawa Pharmaceutical Co., Ltd.		Abstract only
	79	WO	1992/013569	08-20-1992	Galena		
	80	WO	1993/007150	04-15-1993	Sandoz-Erfindungen Verwaltungsgesellschaft M.B.H.		
	81	WO	1994/018317	08-18-1994	The Board of Trustees of the Leland Stanford Junior University		
	82	WO	1994/025606	11-10-1994	Sandoz-Patent GMBH		Abstract only
	83	WO	1995/002684	01-26-1995	The Board of Trustees of the Leland Stanford Junior University		
	84	WO	1996/006111	02-29-1996	Ariad Gene Therapeutics, Inc.		
	85	WO	1996/006857	03-07-1996	Wisconsin Alumni Research Foundation		
	86	WO	1996/027607	09-12-1996	Leiras Oy Lundell		
	87	WO	1996/040758	12-19-1996	Abbott Laboratories		
	88	WO	1997/004005	02-06-1997	C-Chem AG		Abstract only
	89	WO	1997/011092	03-27-1997	Nippon Shinyaku Co., Ltd.		Abstract only
	90	WO	1997/046575	12-11-1997	Poli Industria Chimica, S.P.A.		
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Examiner Initials [*]	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ <i>(if known)</i>				
	91	WO	1998/003192	01-29-1998	Intrabiotics Pharmaceuticals, Inc.		
	92	WO	1998/007713	02-26-1998	Enzon, Inc.		
	93	WO	1998/008956	03-05-1998	President and Fellows of Harvard College		
	94	WO	1998/046247	10-22-1998	Wisconsin Alumni Research Foundation		
	95	WO	1998/049193	11-05-1998	Rhone-Poulenc Rorer S.A.		Abstract only
	96	WO	1998/058927	12-30-1998	Baker Norton Pharmaceuticals, Inc.		
	97	WO	1999/002659	01-21-1999	Biochemie Gesellschaft M.B.H.		
	98	WO	1999/010373	03-04-1999	Wisconsin Alumni Research Foundation		
	99	WO	1999/010374	03-04-1999	Wisconsin Alumni Research Foundation		
	100	WO	1999/021879	05-06-1999	Intrabiotics Pharmaceuticals, Inc.		
	101	WO	1999/032512	07-01-1999	Rhone-Poulenc Rorer S.A.		Abstract only
	102	WO	1999/062540	12-09-1999	Novartis AG		
	103	WO	1999/067280	12-29-1999	Rhone-Poulenc Rorer S.A.		Abstract only
	104	WO	2000/001715	01-13-2000	Debiopharm S.A.		Abstract only
	105	WO	2000/008033	02-17-2000	The University of Kansas		
	106	WO	2000/051558	09-08-2000	The Procter & Gamble Company		
	107	WO	2000/067801	11-16-2000	University of Kentucky Research Foundation		
	108	WO	2001/005819 A1	01-25-2001	Kuhnle Pharm. Co., Ltd.		
	109	WO	2001/013957 A2	03-01-2001	Cellgate, Inc.		
	110	WO	2001/035913 A1	05-25-2001	LG Chemical Co., Ltd.		
	111	WO	2001/035914 A1	05-25-2001	LG Chemical Co., Ltd.		
	112	WO	2002/024865 A2	03-28-2002	Microbia, Inc.		
	113	WO	2002/041858 A1	05-30-2002	LG Household & Health Care Ltd.		
	114	WO	2002/041859 A1	05-30-2002	LG Household & Health Care Ltd.		
	115	WO	2002/064106 A1	08-22-2002	LG Household & Health Care Ltd.		
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				Application Number		10/802,013	
				Filing Date		March 16, 2004	
				First Named Inventor		Molino	
				Group Art Unit		1654	
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		Country Code ³	Number ⁴ (if known)				
	116	WO	2002/065986 A2	08-29-2002	Cellgate, Inc.		
	117	WO	2002/067917 A1	09-06-2002	Cellgate, Inc.		
	118	WO	2002/076927 A2	10-03-2002	Bayer Aktiengesellschaft		Abstract only
	119	WO	2002/085928 A2	10-31-2002	Debiopharm S.A.		Abstract only
	120	WO	2002/092032 A1	11-21-2002	LG Household & Health Care Ltd.		
	121	WO	2002/092033 A1	11-21-2002	LG Household & Health Care Ltd.		
	122	WO	2003/034980 A2	05-01-2003	New River Pharmaceuticals Inc.		
	123	WO	2003/049772 A2	06-19-2003	The Board of Trustees of the Leland Stanford Junior University		
	124	WO	2003/070755 A2	08-28-2003	SYNT:EM		Abstract only
	125	WO	2004/082629 A2	09-30-2004	Albany Molecular Research, Inc.		
	126	WO	2004/096236 A2	11-11-2004	Gilead Sciences, Inc.		
	127	WO	2004/100960 A2	11-25-2004	Gilead Sciences, Inc.		
	128	WO	2005/021028 A1	03-10-2005	Hijikata et al.		
	129	WO	2005/046575 A2	05-26-2005	Signature Pharmaceuticals, LLC		
	130	WO	2005/097164 A2	10-20-2005	Waldmeier		
	131	WO	2006/005580 A1	01-19-2006	Novartis AG		
	132	WO	2006/005610 A1	01-19-2006	Novartis AG		
	133	WO	2006/014872 A2	02-09-2006	AMR Technology, Inc.		
	134	WO	2006/063470 A1	06-22-2006	Isotechnika Inc.		
	135	WO	2006/066416 A1	06-29-2006	Isotechnika Inc.		
	136	WO	2006/071618 A1	07-06-2006	Novartis AG		
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ²
	137	AEBI et al., "Synthesis, Conformation, and Immunosuppressive Activities of Three Analogues of Cyclosporin A Modified in the 1-Position," <i>Journal of Medicinal Chemistry</i> 33(3):999-1009 (1990)					Abstract only
	138	AGATHOS et al., "Enhancement of Cyclosporin Production in a Tolypocladium inflatum Strain After Epichlorohydrin Treatment," <i>Journal of Biotechnology</i> 13(1):73- 81 (1990)					Abstract only
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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	139	AGATHOS et al., "The Fungal Production of Cyclosporins," <i>Annals of the New York Academy of Sciences</i> , 506(Biochem. Eng. 5):657-662 (1987)			Abstract only
	140	ALBERG et al., "Structure-Based Design of a Cyclophilin-Calcieneurin Bridging Ligand," <i>Science</i> (Washington, DC, United States) 262(5131):248-250 (1993)			Abstract only
	141	ANDRES et al., "Interaction of Lead(II) With Highly-Dentate Linear and Cyclic Polyamines," <i>Journal of the Chemical Society, Dalton Transactions: Inorganic Chemistry</i> (23):3507-3513 (1972-1999) (1993)			Abstract only
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	145	BELSHAW et al. "Cell-Specific Calcineurin Inhibition by a Modified Cyclosporin," <i>Journal of the American Chemical Society</i> 119(7):1805-1806 (1997)			Abstract only
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	149	BENCINI et al., "Synthesis and Ligational Properties of the Two Very Large Polyazacycloalkanes [33]aneN11 and [36]aneN12 Forming Trinuclear Copper(II) Complexes," <i>Inorganic Chemistry</i> 27(1):176-180 (1988)			Abstract only

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				Examiner Name	Marcela M. Cordero Garcia
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	150	BENCINI et al., "Thermodynamic and Structural Aspects of the Interaction Between Macrocyclic Polyammonium Cations and Complexed Anions," <i>Inorganic Chemistry</i> 31(10):1902-1908 (1992)			Abstract only
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	154	BROOKS et al., "Preparative Chromatographic Purification of Cyclosporine Metabolites," <i>Clinical Chemistry</i> (Washington, DC, United States) 39(3):457-466 (1993)			Abstract only
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	172	DURETTE et al., "A study of the Correlation Between Cyclophilin Binding and in Vitro Immunosuppressive Activity of Cyclosporine A and Analogs," <i>Transplantation Proceedings</i> 20(2, Suppl. 2):51-57 (1988)			Abstract only
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	196	HUBLER et al., "Synthetic Routes to NETXaa4-Cyclosporin A Derivatives as Potential Anti-HIV I Drugs," <i>Tetrahedron Letters</i> 41(37):7193-7196 (2000)			Abstract only
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	210	LEE et al., "Synthesis and Immunosuppressive Activities of Conformationally Restricted Cyclosporin Lactam Analogs," <i>International Journal of Peptide & Protein Research</i> 35(5):481-494 (1990)			Abstract only
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				First Named Inventor	Molino
				Group Art Unit	1654
				Examiner Name	Marcela M. Cordero Garcia
Sheet	15	of	19	Attorney Docket Number	2809/1331
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	229	PAPAGEORGIOU et al., "Anti HIV-1 Activity of a Hydrophilic Cyclosporine Derivative With Improved Affinity to Cyclophilin," <i>Bioorganic & Medicinal Chemistry Letters</i> 6(4):497 (1996) [Erratum]			Abstract only
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	240	POHL et al., "Crystal Structures of Two Modifications of [3,O-Didehydro-MeBmt1,Val2]Cyclosporin and Comparison of Three Different X-Ray Data Sets," <i>Helvetica Chimica Acta</i> 78(2):355-366 (1995)			Abstract only
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	247	ROEDL et al., "Lipoprotein-Induced Modulation of Cyclosporine A-Mediated Immunosuppression," <i>European Journal of Clinical Investigation</i> 20(3):248-252 (1990)			Abstract only
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	249	ROTHBARD et al., "Conjugation of Arginine Oligomers to Cyclosporin A Facilitates Topical Delivery and Inhibition of Inflammation," <i>Nature Medicine</i> New York 6(11):1253-1257 (2000)			Abstract only
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